IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WYETH, Plaintiff, v. IMPAX LABORATORIES, INC., Defendant.	)	C. A. No. 06-222 (JJF)

WYETH'S ANSWERING BRIEF IN OPPOSITION TO DEFENDANT IMPAX LABORATORIES, INC.'S MOTION TO MODIFY SCHEDULING ORDER

MORRIS, NICHOLS, ARSHT & TUNNELL LLP
Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
Julia Heaney (#3052)
1201 N. Market Street
Wilmington, DE 19899-1347
(302) 658-9200
jheaney@mnat.com
Attorneys for Plaintiff Wyeth

OF COUNSEL:

Basil J. Lewris
Linda A. Wadler
Finnegan, Henderson, Farabow,
Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, DC 20001
(202) 408-4000

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I. INTRODUCTION

Scheduling orders and their enforcement by the Court "are regarded as the essential mechanism for cases becoming trial-ready in an efficient, just and certain manner. The control of these schedules is deliberately reposed in the court, and not in counsel, so that this end may be achieved." *Rouse v. Farmers State Bank*, 866 F. Supp. 1191, 1198 (N.D. Iowa 1994) (*quoting Kramer v. The Boeing Co.*, 126 F.R.D. 690, 692 (D. Minn. 1989)); *Moore's Federal Practice - Civil* 16.14[1](a) n.3 (*quoting Rouse*). In essence, Impax simply disagrees with the Court's phasing of the case, and seeks to move the amendment of pleadings deadline *seven months*, to the end of fact discovery. Moreover, Impax seeks to pin the blame on Wyeth for Impax's disagreement with the Court's schedule. Impax's mud-slinging rhetoric is not only inaccurate but, more importantly, has no relevance to the issue of whether Impax has demonstrated good cause for a seven-month extension of the schedule.

Impax cannot demonstrate good cause because it already has amended its answer, and thus has no current need to modify the scheduling order. Should Impax have good cause for a further amendment in the future, it can move for leave to amend at that time, so long as it satisfies the requirements of Fed. R. Civ. P. 15 and 16(b).

What Impax really seeks by its present motion is to avoid the good cause requirement of Rule 16 for any hypothetical amendments that Impax might wish to file, up to almost the end of fact discovery. Under its proposed new deadline for amending the pleadings, there is no disincentive for Impax to wait until the last possible minute to amend its pleadings and thereby gain a strategic advantage. Such a schedule is contrary to the phasing of the Court's Order and would severely impede the parties' ability to take timely discovery on any such new allegations. Moreover, Impax does not cite a single

case in its brief to support its request to absolve itself of the need to be diligent in seeking leave to amend.

In short, Impax has no basis to challenge this Court's sound discretion in managing this case. Impax's motion is much ado about nothing, and should be denied.

II. STATEMENT OF FACTS

A. Impax's Infringement Of The Patents In Suit

Wyeth filed this action against Impax to prevent Impax from infringing its patents by marketing a generic copy of Effexor® XR before the expiration of the patents-in-suit. The extended release venlafaxine formulation Effexor® XR (Wyeth's widely-popular, commercial embodiment of the patents-in-suit) is used in the treatment of major depressive disorder, generalized anxiety disorder, social anxiety disorder, and panic disorder. Impax infringes at least one method claim of the '171 patent, the '958 patent and the '120 patent. In general, the asserted method claims are directed to orally administering, to a patient in need of venlafaxine treatment, a once-a-day extended release formulation of venlafaxine hydrochloride that provides therapeutic blood concentrations of venlafaxine over a 24-hour period, and that further provides either peak blood plasma levels of venlafaxine occurring within a certain time period or peak blood plasma levels of venlafaxine of no more than a certain concentration level.

Impax's sole basis for alleging non-infringement is the absence in its formulation of an ingredient that does not appear in, and is not required by, the asserted method claims. The use of Impax's formulation literally falls within the language of at least the asserted claims. Moreover, even under the vacated claim construction from the Teva

litigation[1] to which Impax doggedly clings, Impax still infringes under the doctrine of equivalents.

B. Impax's Ill-Founded Bases For Its Allegations Of Inequitable Conduct

Impax attempts to sully Wyeth by relying upon its *already-pled* allegations of inequitable conduct as a basis to extend the amendment deadline. Not only are these allegations ill-founded, but they contravene both the benefits of the claimed invention relative to use of the immediate release dosage form, as well as the New Jersey court's assessment of those allegations in a hearing transcript from the Teva litigation listed on the docket as publicly available well in advance of Impax's original answer, let alone its amended one.

1. Impax Ignores That Reduction In Nausea And Vomiting Is A Primary Reason For The Commercial Success Of Wyeth's Effexor® XR

Impax's allegations are founded on the ill-conceived premise that the patents-in-suit misrepresent that an extended release venlafaxine dosage form of the invention provides a statistically significant improvement over the conventional immediate release formulation of the drug. But in making its charge, Impax ignores that the commercial embodiment of the claimed invention, Effexor® XR, has been a phenomenal commercial

[1] *Wyeth v. Teva Pharmaceuticals USA, Inc., and Teva Pharmaceutical Industries Ltd.*, Civil Action No. 03-1293 (WJM) in the United States District Court of the District of New Jersey. Wyeth notes that Impax's Paragraph IV certification notice letter, which provoked this litigation, is entirely premised upon a vacated Markman ruling from the Teva litigation. Wyeth asserts that the Markman ruling was erroneous as a matter law, violating the most basic tenets of claim construction. The numerous errors in the ruling include reading into claims ingredients that were not recited in those claims, discounting the doctrine of claim differentiation, ignoring the ordinary meaning of the broad claim term "extended release formulation," and giving no weight to unambiguous prosecution history that directly supports giving "extended release formulation" its ordinary meaning.

success as a result of its once-a-day dosing and improved tolerability. The immediate-release dosage form of venlafaxine, Effexor®, which required multiple daily dosing, suffered from tolerability problems due to its propensity to cause nausea and vomiting, resulting in its pejorative nickname "Side-Effexor." As a result of these problems, U.S. sales of Effexor® flattened at about $200 million per year. By comparison, sales of Wyeth's once-a-day extended-release dosage form of venlafaxine, Effexor® XR, have risen since its launch in November 1997 to annual sales today well over $2 billion in the U.S. Since both Effexor® and Effexor® XR contain the same active ingredient, venlafaxine hydrochloride, it is clear that the phenomenal commercial success is directly attributable to the ability of the extended-release dosage form to overcome the tolerability issues and the problems associated with multiple daily dosing.

The extended release dosage forms of the invention, the use of which is claimed in the patents-in-suit, unlocked the true potential of the venlafaxine molecule as an important therapy for the debilitating conditions of depression, generalized anxiety disorder, social anxiety disorder and panic disorder. Indeed, were it not for the commercial success of Effexor® XR, Impax would hardly be motivated to prematurely market its own, generic copy of Effexor® XR before the expiration of the patents covering it. It is both ironic and telling that Impax relies on one of the substantial benefits of the very product it wants to market to make its baseless inequitable conduct allegations.

2. Impax Provides This Court With Only A Partial Account Of The Public Record In The Teva Litigation, Ignoring Evidence That Impax's Allegations Of Inequitable Conduct Are Baseless

As Impax admits, Impax based its inequitable conduct allegations in its amended answer on the "public record," which, according to Impax, "includes papers filed in" the prior Teva litigation. Impax Br. at 2 n. 2; D.I. 35. Impax appears to have based its inequitable conduct allegations on those made by Teva in its motion to amend its answer to include inequitable conduct. Matterer Decl., D.I. 37, Ex. 4. Specifically, Impax parrots Teva's allegations that a statement in the patents-in-suit at col. 2, ll. 52-55 that "Venlafaxine ER showed statistically significant improvement over conventional venlafaxine hydrochloride tablets in two eight-week and one 12-week clinical studies" was a misrepresentation because, according to Impax, "the studies cited showed no such thing." Impax Br., D.I. 35 at 4.

Impax fails to mention, however, that during the final May 9, 2005 hearing on Teva's motion to amend, Magistrate Judge Shwartz of the New Jersey District Court recognized the improvement in the nausea and vomiting adverse event profile of extended release venlafaxine relative to immediate release venlafaxine. She further recognized that the statement in the patents-in-suit referring to statistical significance does not exclude pooling the data from all three clinical studies; and that it was undisputed that when data from the three clinical studies are pooled:

> Wyeth's conclusions . . . about nausea and emesis in the ER versus IR study was founded. The language of the patent application does not say that each of the three taken individually shows an improvement in incidence of nausea and emesis in the venlafaxine ER versus IR. It certainly does not exclude the connotations that the studies were pooled together to support the conclusion . . . .

* * *

> The statement does not say the isolated results of each study showed an improvement in the incidence of nausea and emesis in the venlafaxine ER versus IR. They name the three studies taken together, it's been represented, support the statement's conclusion and is not a misrepresentation. Therefore, the Court is not sure that a reasonable examiner would find the lack of information to have been material.

Michelsohn Decl., Ex. 2, Hearing Tr. at 100-101. Magistrate Judge Shwartz then further concluded:

> Thus, Teva's allegation, at least in my view, may not have withstood a 12(b)(6) motion and the proposed amendment would, therefore, have been deemed futile, had the Court reached the Rule 15 analysis [after denying Teva's motion to amend under Rule 16].

Id. at 101.

Magistrate Judge Shwartz's analysis, like Teva's allegations, are docketed as being publicly available in May 2005 well before Impax filed its original pleading, let alone its amended one. Michelsohn Decl., Ex. 1, Teva Litigation Docket at p. 8, entry 85. Yet Impax chose to include in its amended pleading and in its current motion only those portions of the public record that purportedly favor it, and ignores those portions that clearly undermine Impax's position. Indeed, Impax does not explain why it could not have obtained any of this information, including that on which it based its amended answer, well in advance of its original pleading.

Finally, Impax refers to "at least one further theory of inequitable conduct" that Teva alleged, but claims that "Impax is not in a position to investigate whether this second theory of inequitable conduct is sound." Impax Br., D.I. 35 at 5. Specifically, Impax points to Teva's allegation that Wyeth "overstated the difference in water

solubility between its drug venlafaxine hydrochloride and Teva's propranolol hydrochloride" to the PTO. Matterer Decl., D.I. 37, Ex. 4 at 1 n.3. Impax had access to the publicly available file histories of the patents-in-suit, as well as to treatises on the physio-chemical properties of venlafaxine and propranolol. With these publicly available sources in hand, Impax has no need for discovery from Wyeth to know that this allegation is baseless.

Impax's attempts to paint Wyeth as a "bad actor" with its charges of inequitable conduct thus provide no basis to change the Court's Scheduling Order.

C. Impax Blames Wyeth For Its Own Disagreement With This Court's Management Of The Case Schedule

Impax further attempts to justify its unwarranted challenge to this Court's case management schedule by blaming Wyeth for alleged wrongs arising from Impax's own actions. Impax first faults Wyeth for not challenging this Court's Scheduling Order stating:

> immediately after the Court issued its Scheduling Order, Impax requested that Wyeth agree to stipulate to a modification of the Scheduling Order to give the parties time to resolve these disputes. Wyeth has repeatedly refused to agree to an extension to alleviate the prejudice caused by Wyeth's dilatory conduct.

Impax Br., D.I. 35 at 7.

The parties were unable to agree on a schedule in this case and thus submitted their competing proposals to the Court. D.I. 17 and 18. As Wyeth explained to Impax, Wyeth declined to stipulate to such an extension due to its understanding that the Court had entered the current Scheduling Order after considering the competing proposals of the parties, and that the Order reflected the Court's views as to how the case should be

managed. Matterer Decl., D.I. 37, Ex. 14. There is nothing improper about Wyeth not joining in the requested extension.

Impax next contends that Wyeth has taken actions in discovery that impaired its ability to respond to the amendment deadline and somehow justify a seven-month extension.[2] Impax Br., D.I. 35 at 5. This Court's Scheduling Order did not envision the necessity for complete document discovery prior to the August deadline for amendment of pleadings. Document production is not scheduled for completion until October. Moreover, as demonstrated below, the conduct about which Impax complains is of Impax's own doing. Wyeth's inability to meet Impax's demand of producing the entire 86,000 page NDA file in paper form in four business days is due to Impax's wholly unreasonable deadline. Furthermore, Wyeth's inability to immediately provide the remainder of the requested materials is due to Wyeth's obligation to ensure Teva confidential information is not inappropriately disclosed in violation of a Protective Order. Wyeth cannot be faulted for either of these things and they provide no basis for modifying the amendment deadline.

1. Impax Blames Wyeth For Not Producing More Than 86,000 Pages Within Impax's Unilaterally Imposed Four Day Deadline

While Impax claims that it has not had adequate time to review documents, Impax waited *eighteen* days after issuance of the Court's Scheduling Order to demand expedited production of Wyeth's entire NDA in less than *four* days. Specifically, after the close of business on July 31, 2006, Impax demanded that Wyeth produce, within four days (by

[2] Wyeth does not address here the allegations raised by Impax at page 6 of its brief because they are the subject of Impax's separate motion to compel (to which Wyeth has formally responded) and have nothing to do with the subject matter of this motion.

August 4, 2006), Wyeth's entire NDA file in paper format consisting of more than 86,000 pages as well as multiple papers from the Teva litigation. Michelsohn Decl., Ex. 3. Impax further stated that if Wyeth did not comply with its request, it would move to compel and or alter the Scheduling Order. *Id.* Impax imposed this artificial discovery deadline on the very day that Wyeth's responses to the majority of Impax's document requests were due and more than two months before the October deadline set by this Court for the close of document discovery.

Even though Wyeth's production was not yet due, Wyeth produced a complete production copy of Wyeth's NDA within one week. Promptly after Wyeth's expedited production began, Impax changed its tune, stating "[r]egardless of whether Impax is able to obtain discovery from Wyeth prior to the August 10 deadline, we are prepared to file an Amended Answer and Counterclaim." Matterer Decl., D.I. 37, Ex. 21 at 2. Impax made no mention at that time that further information was still needed or that it was exploring alternative theories. Indeed, Wyeth stipulated to the filing of the amendment, and the Court granted leave to file on August 16, 2006. Yet, Impax now seeks ***carte blanche*** to further amend its pleadings at any time through the end of March, purportedly because Wyeth produced its entire NDA file in one week rather than four days.

Impax now argues that "[t]here is no justification for Wyeth's producing its NDA in a 'rolling production,'" because "[d]espite the length of the NDA [over 86,00 pages], it . . . can be produced in one day as a package, as images burned onto a compact disc," and points to its production of its ANDA of only approximately 4500 pages. Impax Br., D.I. 35 at 12. Impax's argument ignores the simple fact that Impax specifically stated it

was only willing to accept "paper copies of these documents," not TIFF images.[3] Michelsohn Decl., Ex. 3 at 2.

Furthermore, Impax's allegation that Wyeth's NDA was produced "as an unorganized mass of paper calculated to deprive Impax of the opportunity for meaningful analysis" simply is not true. Wyeth's NDA was produced as it was kept in the ordinary course of business. The very first box produced to Impax contains a detailed guide to the organization of the originally-filed NDA (WYETH004-000029-36), an index to the table of contents, (WYETH004-000038) and a detailed table of contents noting the volume and page number of various parts of the submission (WYETH004-000039-66). Subsequent pages in the production are also organized according to volume numbers. Wyeth's production further contains a section regarding MedWatch reports, followed by Wyeth's internal "shelf volumes" concerning supplemental filings and correspondence.

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[3] Impax further criticizes Wyeth for seeking the payment *that Impax had promised* for copies of those documents. Impax represented in its July 31st letter that "Impax is willing to accept ***paper*** copies of these documents and to pay for the reasonable cost of producing these documents" (emphasis added). Michelsohn Decl., Ex. 3 at 2. Wyeth responded to Impax on August 2, 2006, specifically pointing out that, "[g]iven the large number of documents involved (over 86,000 pages), your request for production in less than one week is not reasonable," but agreed to begin producing the documents, and accepted Impax's offer to pay for the paper copies. Matterer Decl., D.I. 37, Ex. 15. Impax waited to respond until Friday, August 4, 2006 at the close of business, reneging on its promise to pay and claiming for the first time that Impax's offer to pay copying costs "was expressly contingent on Wyeth's agreement to produce the documents on an expedited basis." Michelsohn Decl., Ex. 4. at 1. There was no such "express conting[ency]" in Impax's July 31st letter and Impax points to none in its brief.

By the time of Impax's August 4th letter, Wyeth had already incurred the significant expense of complying with Impax's demand. In fact, the first box of Wyeth's NDA was produced to Impax's counsel on Friday, August 4, 2006 via Federal Express, Saturday delivery. The remaining 33 boxes were produced to Impax on Tuesday, August 8, 2006. Matterer Decl., D.I. 37 at Exs. 22 and 23, Michelsohn Decl., Ex. 5. As discussed in Wyeth's Opposition to Impax's Motion to Compel, Impax should be ordered to reimburse Wyeth for the costs of providing a production copy of Wyeth's NDA for Impax.

Finally, Impax alleges that its expedited need for the requested deposition transcripts is due to "the absence of sufficient time (or underlying documents) to take depositions of Wyeth and the inventors of the patents-in-suit." Impax Br., D.I. 35 at 2. Yet this Court's Scheduling Order did not contemplate that depositions would be taken prior to the August deadline for amendment of pleadings. Indeed, depositions are not permitted to begin until October. Rule 16 Scheduling Order, D.I. 27 at ¶ 3(d). Here again, it is Impax, not Wyeth, who is "manufacturing needless discovery disputes" to somehow justify its request to modify the Scheduling Order.

2. Wyeth's Compliance With The Protective Order In The Teva Litigation Provides No Grounds For Modifying The Court's Scheduling Order

As Impax concedes, Wyeth informed Impax early on in its responses to discovery requests that redaction of Teva confidential information would require Teva's input. Impax Br., D.I. 35 at 7. Yet Impax incredibly asserts that there is no undue burden to Wyeth in redacting thousands of pages of documents, because Wyeth purportedly knows what constitutes Teva confidential information. Impax Br., D.I. 35 at 6. There is no magic wand that can instantly perform the arduous task of removing Teva confidential information from the documents. Teva confidential information is sprinkled throughout pleadings and transcripts from the Teva litigation. Moreover, the Teva litigation documents were marked confidential as a whole, not by page and line number as Impax implies. Thus, Wyeth does not know which portions of the documents Teva considered to be confidential at the time they were marked, or what Teva's current position on their confidential status might be. As a result, Teva will have to do much of the painstaking and time consuming line-by-line redaction of its own confidential information. Impax should not be allowed to force Wyeth to jeopardize its compliance with the protective

order in the Teva litigation by setting artificial and arbitrary deadlines, and then demanding that Wyeth meet those deadlines by making unilateral decisions concerning the confidentiality of Teva information.

Impax's assertion that "[d]ue to Wyeth's refusal to produce even those documents that clearly contained only Wyeth confidential information, Impax was forced to list [in a letter to Teva counsel] such documents as the deposition transcripts of Wyeth's 30(b)(6) witnesses and the inventors of the patents-in-suit" [Impax Br., D.I. 35 at 9] is simple revisionist history. Wyeth *agreed* to produce the deposition transcripts of Wyeth fact witnesses in its July 26, 2006 responses to Impax's discovery requests. Matterer Decl., D.I. 37, Ex. 7 at 10 and 12. Notwithstanding this agreement, Impax wrote Teva counsel on August 1st asking whether those transcripts contained Teva confidential information. As a result, Wyeth counsel wrote to Impax counsel the next day indicating that they would "wait to hear Teva's response before production of those deposition transcripts" to give Teva an opportunity to respond. Matterer Decl., D.I. 37, Ex. 15 at n. 1. Wyeth now has produced the deposition transcripts of the inventors and two 30(b)(6) witnesses Impax requested on an expedited basis.[4]

[4] Impax further complains that deposition and hearing transcripts are not listed on the docket for the Teva litigation. Impax ignores, however, that Wyeth *agreed from the outset* to produce the deposition transcripts of Wyeth's fact witnesses as well as exhibits marked during those depositions. Impax has no need for a list of the Teva fact witnesses that were deposed because such testimony, concerning a different party and product, is irrelevant to this litigation. The hearing transcripts from the Markman hearing and on Teva's motion for leave to amend its answer alleging inequitable conduct are listed on the docket as publicly available. Michelsohn Decl., Ex. 1 at Teva Litigation Docket pp. 8 and 11, entries 85 and 123 respectively. As a result, there was and is no need for Impax to seek these documents through Wyeth. Impax has not articulated how other hearing transcripts concerning discovery disputes or infringement that are specific to other parties and products are of any relevance to the present litigation.

Finally, Impax argues that Wyeth's assertion that Teva's proposed amended answer contains Teva confidential information is "mere pretext for its refusal to produce this document." Impax Br., D.I. 35 at 10. What Impax ignores is that Wyeth's Amended Complaint, to which Teva's proposed amended answer responds, does contain Teva confidential information and, thus, was filed under seal. As a result, Teva's proposed amended answer contains Teva confidential information, the confidential status of which Teva may wish to preserve.

III. ARGUMENT

A. Impax Has Not Shown "Good Cause" Under Rule 16(b) To Modify The Court's Scheduling Order

1. Rule 16(b) Imposes A "Good Cause" Requirement

Once a scheduling order has been entered, Rule 16(b) of the Federal Rules of Civil Procedure governs amendment of pleadings. *Eastern Minerals & Chemicals Co. v. Mahan*, 225 F.3d 330, 340 (3d Cir. 2000). Modification of the scheduling order under Rule 16(b) to amend pleadings after the date set in the order for doing so requires a moving party to show "good cause" and that the amendment is proper under Rule 15. *Id.*; Fed. R. Civ. P. 16(b); *Johnson v. Mammoth Recreations, Inc.*, 975 F.2d 604, 609 (9th Cir. 1992) ("'A court's evaluation of good cause is not coextensive with an inquiry into the propriety of the amendment under . . . Rule 15.'") Impax itself recognizes that modification of the scheduling order in this case now under Rule 16(b) would only be proper "'upon a showing of good cause . . . .'" Impax Br., D.I. 35 at 12 (*quoting* Rule 16(b)). Impax has not shown any "good cause" to modify the scheduling order.

2. There Is No "Good Cause" Now To Extend A Scheduling Order By Seven Months To Allow Hypothetical Amendments That Do Not Exist

Impax has already amended its pleading. It has no new amendment over which the issue of good cause could even arise. One simply cannot show good cause to enter, in the future, theoretical amendments that do not now exist.

By bringing its motion now, what Impax really seeks is for this Court to extend the deadline for amending the pleadings seven months until the end of March, without being subject to the "good cause" requirement of Rule 16(b)–*i.e.*, without having to demonstrate that it was diligent in bringing its motion after discovering evidence that it could not have known about previously that would support an amended pleading. *See* Committee Note to 1983 Amendment to Fed. R. Civ. P. 16 ("[T]he court may modify the schedule on a showing of good cause if it cannot reasonably be met despite the diligence of the party seeking the extension."); *Globespanvirata, Inc. v. Texas Instruments Inc.*, C.A. No. 03-2854 (GEB) 2005 WL 1638136 (D.N.J. July 25, 2005) ("Under Rule 16, modifying a Court's scheduling order is only appropriate when the movant shows that deadlines could not be met despite its diligence.").

If Impax has a new amendment to offer, it can move for leave to amend at that time. Impax's motion is plainly premature. Impax has no new amendment, and thus has no good cause for seeking leave to enter it. Permitting amendments to be freely filed until the end of fact discovery would pose the risk of upsetting the preexisting discovery schedule the Court already has set in place and absolve Impax of its need to be diligent in seeking leave to amend.

3. Impax's So-Called "Diligence" In Demanding Unreasonably Early Document Production By Wyeth Does Not Provide Good Cause for Modification of the Scheduling Order

Impax claims that it "has been diligent in investigating whether it may have further defenses or counterclaims prior to the August 10 deadline." Impax Br., D.I. 35 at 1. Impax's "diligence," however, consists not in promptly moving this Court to amend pleadings after learning of new evidence, but rather in trying to harass Wyeth with unreasonable discovery demands that ignore this Court's phasing of the case and imposing schedules of Impax's own making.

This Court entered its Scheduling Order on July 13, 2006, calling for document discovery to be completed in October, roughly two months after the deadline set for amendment of pleadings. Thus, the Court's Order envisions that discovery would be ongoing after the deadline for amending pleadings had passed. Nothing in the Scheduling Order required Wyeth to comply with Impax's artificial four-day deadline. Impax also does not explain why it would have been able to comply with the Court's Scheduling Order had Wyeth produced its NDA file in four business days rather than the one week the enormous production actually took.

While Impax further complains that it purportedly needed deposition transcripts and pleadings from the Teva litigation, nowhere does Impax provide any authority for the proposition that it is entitled to deposition testimony two months in advance of the completion of document discovery. Indeed, under the Court's Scheduling Order, depositions may not even begin until October. Nonetheless, Impax faults Wyeth for attempting to comply with the protective order in the Teva litigation, by giving Teva an opportunity to redact its own confidential information.

IV. CONCLUSION

In sum, Impax's demands on Wyeth and Impax's complaints about Wyeth's alleged failure to meet them is a side-show having nothing to do with whether Impax has any basis for so radically altering the Court's schedule. Impax's attempts to force its unilaterally accelerated discovery schedule upon Wyeth provides no substance to Impax's argument for leave, but instead merely seeks to blame Wyeth for Impax's disagreement with this Court's management of the case schedule.

Moreover, Impax's demand that this Court extend the deadline to amend pleadings by seven months until nearly the end of fact discovery would severely prejudice Wyeth by foreclosing to Wyeth discovery of Impax's knowledge about the allegations it may choose to make after the close of document discovery. Impax should not be permitted to limit Wyeth's discovery efforts as to as-of-yet undefined claims while Impax obtains the benefit of being able to make those claims without a showing of good cause throughout most of the fact discovery period. Because it has already amended its answer, and has no good cause at this time for any further amendments, its attempt to modify the Scheduling Order should be denied.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Julia Heaney (#3052)

Jack B. Blumenfeld (#1014)
Karen Jacobs Louden (#2881)
Julia Heaney (#3052)
1201 N. Market Street
Wilmington, DE 19899-1347
(302) 658-9200
jheaney@mnat.com
Attorneys for Plaintiff Wyeth

OF COUNSEL:

Basil J. Lewris
Linda A. Wadler
Finnegan, Henderson, Farabow, Garrett & Dunner, L.L.P.
901 New York Avenue, N.W.
Washington, DC 20001
(202) 408-4000

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534169

CERTIFICATE OF SERVICE

I, Julia Heaney, hereby certify that on August 24, 2006 I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing(s) to the following:

Mary B. Matterer
MORRIS, JAMES, HITCHENS & WILLIAMS, LLP

and I further certify that copies were caused to be served upon the following in the manner indicated:

BY HAND

Mary B. Matterer
Morris, James, Hitchens & Williams
222 Delaware Avenue
P.O. Box 2306
Wilmington, DE 19899

BY FEDERAL EXPRESS

M. Patricia Thayer
John M. Benassi
Jessica R. Wolf
Heller Ehrman LLP
4350 La Jolla Village Drive
San Diego, CA 92102

/s/ Julia Heaney (#3052)
Julia Heaney (#3052)